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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/251,638 02/17/99 DANIELL

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022469 HM12/0808
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EXAMINER

KUBELIK, A

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED:

08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application N .	Applicant(s)
	09/251,638	DANIELL, HENRY
	Examiner	Art Unit
	Anne Kubelik	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on interview of 06/27/01.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 17 February 1999 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). 8.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

1. Claims 1-2 from the first of the two sets of claims were cancelled, as requested by Applicant. The remaining set of claims, claims 1-6, are examined.

Drawings

2. Drawings are to be submitted on separate sheets of paper, as described in MPEP 608.02 and 37 CFR 1.84. Drawings are not to be incorporated into the text of the specification as they are in journal articles. Additionally, the drawings in the text portion of the specification are illegible. Correction is required.

Specification

3. A substitute specification not including the claims is required pursuant to 37 CFR 1.125(a) because of letter quality, margin size, type size and format errors in the specification as filed.

The following are missing:

A brief description of the drawings.

An abstract of the disclosure.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the

amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

4. Sequence identifiers must accompany all mentions of a sequence in the claims and the specification (See MPEP 2422.03 and 37 CFR 1.821(d)).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to plants transformed with a protein based polymer, where the plants have improved water absorption, thermal characteristics, fiber strength and chemical reactivity.

The instant specification, however, fails to provide guidance for transformation with a protein, as claimed in claims 1-2. Currently, transformation can only be performed with nucleic acids.

Presumably, what was intended to be claimed were cotton plants transformed with a gene encoding a protein based polymer. However, there is unpredictability associated with expression of protein based polymer genes in plants. Zhang et al (1995, Biotechnol. Lett. 17:1279-1284) teach that translation of glycine-rich polymer transcripts was reduced in heterotrophic tissues

because of the limited availability of glycine (pg 1283, last paragraph). As cotton fibers from plants transformed with a gene encoding a protein based polymer were not analyzed for improved water absorption, thermal characteristics, fiber strength and chemical reactivity, the unpredictability associated with expression of protein based polymer genes has not been overcome.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for plants transformed with a protein based polymer or a protein based polymer gene, where the plants have improved water absorption, thermal characteristics, fiber strength and chemical reactivity.

7. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The expression cassette of claim 6 is not described, as no gene sequence is provided, no gene is named or characterized, and no polymer is characterized in any way (even to the extent of what kind of polymer is being referred to).

The protein based polymer genes of the expression cassettes of claims 3-4 are not described, other than that the cassette of claim 4 presumably encodes a protein that comprises GVGVP. The rest of that protein is not described. The protein based polymer [gene]s transformed into the plants of claims 1-2 are not described.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

8. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim 1 is indefinite for its recitation of "exhibiting improved...binding." It is not clear if this phrase is intended to modify "polymer" or "cells" or "plant".

In claim 1 it is not clear which thermal characteristics and chemical reactivities are being referred to nor is it clear what characterizes "improved" water absorption, thermal characteristics, or chemical reactivities (e.g., is less or more water absorption considered "improved"?). Additionally, the term "improved" in claim 1 is a relative term that renders the claim indefinite. The term "improved" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. What the plant, cell or polymer (see above) is improved relative to is not clear.

Claim 1 either needs an --and-- within its list of all properties that are improved, or the properties need to be listed in Markush format (in which case an --and-- is still required).

Regarding claim 1, the phrase “including” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 3 recites the limitation “the protein based polymer gene” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation “the gene” in line 1, the limitation “the gene sequence” in line 2, and the limitation “the polymer” in line 3. There is insufficient antecedent basis for these limitations in the claim.

Claim 6 is generally incomprehensible. For example, it is not clear as to what “physical/chemical properties of the polymer could be altered at will” means or is referring to.

Claims 5 and 6 have the error that the first word is “As” instead of --An--.

Claim 3 is indefinite for its recitation of “balanced by” It is unclear if the terminator, selectable marker genes, and regulatory regions are intended to balance the weight of the protein based polymer gene or if “balanced” is used to mean something else. The relationship of the regulatory elements to the other features of the expression cassette is also unclear. Note also that there should an --and-- after terminator.

In claims 2 and 4, “contains” should be replaced with --comprises--.

Claims 2 and 4 are indefinite in their recitation of the abbreviation “GVGVP.” For purposes of examination, it was assumed that “GVGVP” referred to “Gly-Val-Gly-Val-Pro.” Such treatment does not relieve Applicant of the responsibility to respond to this rejection. Note also that sequence identifiers must accompany all mentions of a sequence in the claims (See MPEP 2422.03 and 37 CFR 1.821(d)).

Claim 3 is indefinite in its recitation of “promoter driving the protein based polymer gene”. For purposes of examination, it was assumed that what was intended was that the promoter drive the expression of the gene. Such treatment does not relieve Applicant of the responsibility to respond to this rejection.

Claim 4 is indefinite in its recitation of “wherein the gene contains the repetitive amino acid sequence” as genes “contain” nucleotides, not amino acids. The phrase --the protein encoded by-- should be inserted before ‘the gene’. Additionally, “contain” should be replaced with --comprises--. Lastly, there is insufficient antecedent basis for the limitation “the gene” in the claim, as claim 3, upon which claim 4 is dependent, recites “the protein based polymer gene”.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claim 6 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhang et al (1996, *Plant Cell Rep.* 16:174-179).

Zhang et al, 1996, teach an expression cassette encoding the polymer (GVGVP)₁₂₁ (pg 175, left column, paragraph 1, and Fig. 1). The gene in this expression cassette is synthetic and its size and other chemical and physical properties could be changed at will.

11. Claim 6 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Daniell et al (US Patent 6,004,782, filed April, 1995).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Daniell et al teach expression cassettes encoding the polymers (GVGVP)₁₂₀, (VPGVG)₁₉-VPGV, (GGAP)₁₂, (AVGVP)₁₀ (column 16, lines 26-36; column 21, lines 11-23; column 22, lines 4-37). The genes in these expression cassettes are synthetic, and their size and other chemical and physical properties could be changed at will.

12. Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by John (1997, US Patent 5,602,321).

John '321 teaches an expression cassette comprising the fiber-specific promoter E6 (column 11, lines 19-37, and column 24, lines 1-5) and a cotton plant transformed with this expression cassette and ones comprising other fiber-specific promoters (claims 1-12). The genes

that are part of these expression cassettes encode a protein based polymer as all proteins are polymers, would be synthetic, and can be changed at will.

13. Claims 1, 3 and 5-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773).

John et al, 1996, teaches expression cassettes comprising the fiber-specific promoter E6 and cotton plants transformed with this expression cassette and ones comprising other fiber-specific promoters (all of pg 12769). The genes that are part of these expression cassettes encode a protein based polymer as all proteins are polymers, would be synthetic, and can be changed at will.

14. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by John et al (1997, US Patent 5,597,718) in light of John et al (1995, Plant Physiol. 108:669-676).

John et al '718 teach cotton plants transformed with an expression construct comprising a fiber-specific E6 promoter, the protein based polymer H6 and selectable markers (column 20, lines 31-67, column 23, line 15, to column 24, line 6, and Table 4). John et al, 1995, teach that the H6 protein contains a pentapeptide repeat (pg 675, left column, paragraph 3), and is thus a protein based polymer. The cotton fibers from these transgenic plants have improved strength ('718, column 23, line 37, to column 24, line 6, and Table 4) and would have improved water absorption, thermal characteristics and chemical reactivity because of the presence of the H6 protein in secondary cell wall ('718, column 23, lines 22-36). The transgenic plants would contain the amino acid sequence GVGVP somewhere within them.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al (1997, US Patent 5,597,718) in view of Zhang et al, 1996 (*supra*).

The claims are drawn to expression cassettes comprising a fiber specific promoter and a protein based polymer gene encoding (GVGVP)_n and cotton plants transformed with those cassettes.

John et al '718 teach cotton plants transformed with an expression construct comprising a fiber-specific E6 promoter, the protein based polymer H6 and selectable markers (column 20, lines 31-67, column 23, line 15, to column 24, line 6, and Table 4). John et al do not teach a gene encoding (GVGVP)_n.

Zhang et al teach an expression cassette encoding another protein based polymer, (GVGVP)₁₂₁ (pg 175, left column, paragraph 1, and Fig. 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to improve cotton fibers by transformation with a gene encoding one protein based polymer as taught by John et al, and to modify that to use the protein based polymer gene described in Zhang et al. One of ordinary skill in the art would have been motivated to do so because of the agronomic importance of cotton. Use of different genes encoding protein based polymers would be an optimization of desired fiber properties.

17. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773) in view of Zhang et al, 1996 (*supra*).

The claims are drawn to expression cassettes comprising a fiber specific promoter and a protein based polymer gene encoding (GVGVP)_n and cotton plants transformed with those cassettes.

John et al, 1996, teaches expression cassettes comprising the fiber-specific promoter E6 and cotton plants transformed with this expression cassette and ones comprising other fiber-specific promoters (all of pg 12769). These fibers have improved thermal properties and would have improved fiber strength, water absorption, and chemical reactivity (pg 12768, right column, paragraph 1, and pg 12772, right column, paragraph 2-4). John et al does not disclose a gene encoding (GVGVP)_n.

Zhang et al teach an expression cassette encoding another protein based polymer, (GVGVP)₁₂₁ (pg 175, left column, paragraph 1, and Fig. 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to improve cotton fibers by transformation with a gene that results in accumulation of one polymer in the fibers as taught by John '321, and to modify that to use a gene encoding the polymer described by Zhang et al. One of ordinary skill in the art would have been motivated to do so because of the suggestion of John et al to express polymers and other proteins in the fiber (pg 12768, right column, paragraph 1, and pg 12773, left column, paragraph 1).

Conclusion

18. No claim is allowed.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059.

The examiner can normally be reached on Monday through Friday, 8:15 am - 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula K. Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.

August 6, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

